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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,390	RAITANO ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-48 are pending.

2. Applicant is reminded that traversal of a Election Requirement will result in the loss of the "special" status of the application (M.P.E.P. 708.02, VIII, section b).

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-15, in part, drawn to a composition comprising a peptide derived from SEQ ID NO:3, a protein which is at least 90-99% homologous to SEQ ID NO:3, a polynucleotide encoding SEQ ID NO:3 or a peptide derived from SEQ ID NO:3 and a double-stranded siRNA that corresponds to the polynucleotide which encodes SEQ ID NO:3, classified in class 530, subclass 300 and class 536, subclass 23.4 and 24.5.
2. Claims 1-15, in part, drawn to a composition comprising a peptide derived from SEQ ID NO:5, a protein which is at least 90-99% homologous to SEQ ID NO:5, a polynucleotide encoding SEQ ID NO:3 or a peptide derived from SEQ ID NO:5 and a double-stranded siRNA that corresponds to the polynucleotide which encodes SEQ ID NO:5, classified in class 530, subclass 300 and subclass 23.4 and 24.5.
3. Claims 1-15, in part, drawn to a composition comprising a peptide derived from SEQ ID NO:7, a protein which is at least 90-99% homologous to SEQ ID NO:7, a polynucleotide encoding SEQ ID NO:7 or a peptide derived from SEQ ID NO:7 and a double-stranded siRNA that corresponds to the polynucleotide which encodes SEQ ID NO:7, classified in class 530, subclass 300 and class 536, subclass 23.4 and 24.5.
4. Claims 1-15, in part, drawn to a composition comprising a peptide derived from SEQ ID NO:11, a protein which is at least 90-99% homologous to SEQ ID NO:11, a polynucleotide encoding SEQ ID NO:11 or a peptide derived from SEQ ID NO:11 and a double-stranded siRNA that corresponds to the polynucleotide

which encodes SEQ ID NO:11, classified in class 530, subclass 300 and class 536, subclass 23.4 and 24.5.

5. Claims 1 and 14, both in part, drawn to a composition comprising a peptide derived from SEQ ID NO:1, classified in class 530, subclass 300 and class 536, subclass 24.5. It is noted that table VIII on page 135 indicates a series of peptides derived from SEQ ID NO:1. Figure 2 makes no mention of SEQ ID NO:1. Therefore, claims drawn to amino acids of Figure 2 and polynucleotides encoding a protein of Figure 2 are not included in this group. It is further noted that the sequence listing indicates that SEQ ID NO:1 is a polynucleotide rather than a polypeptide.

6. Claims 16-20, 44 and 45, all in part, drawn to a method of generating a mammalian immune response directed to a protein of Figure 2 comprising exposing the cells of the mammal's immune system to a portion of SEQ ID NO:3 or a nucleotide sequence that encodes said portion whereby an immune response is generated, and a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:3 comprising administering a 254P1D6b-related protein of SEQ ID NO:3, or a polynucleotide encoding SEQ ID NO:3,classified in class 514, subclasses 2 and 44.

7. Claims 16-20, 44 and 45 all in part, drawn to a method of generating a mammalian immune response directed to a protein of Figure 2 comprising exposing the cells of the mammal's immune system to a portion of SEQ ID NO:5 or a nucleotide sequence that encodes said portion whereby an immune response is generated, and a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:5 comprising administering a 254P1D6b-related protein of SEQ ID NO:5, or a polynucleotide encoding SEQ ID NO:5, classified in class 514, subclasses 2 and 44.

8. Claims 16-20, 44 and 45 all in part, drawn to a method of generating a mammalian immune response directed to a protein of Figure 2 comprising exposing the cells of the mammal's immune system to a portion of SEQ ID NO:7 or a nucleotide sequence that encodes said portion whereby an immune response

is generated, and a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:7 comprising administering a 254P1D6b-related protein of SEQ ID NO:7, or a polynucleotide encoding SEQ ID NO:7, classified in class 514, subclasses 2 and 44.

9. Claims 16-20, 44 and 45 all in part, drawn to a method of generating a mammalian immune response directed to a protein of Figure 2 comprising exposing the cells of the mammal's immune system to a portion of SEQ ID NO:11 or a nucleotide sequence that encodes said portion whereby an immune response is generated, and a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:11 comprising administering a 254P1D6b-related protein of SEQ ID NO:11, or a polynucleotide encoding SEQ ID NO:7, classified in class 514, subclasses 2 and 44.

10. Claims 21-27 in part, drawn to a method for detecting in a sample the presence of a 254P1D6B-related protein or a 254P1D6B-related polynucleotide comprising contacting the sample with a substance that specifically binds to SEQ ID NO:3 or the polynucleotide encoding SEQ ID NO:3, classified in class 435, subclasses 6 and 7.1.

11. Claims 21-27 in part, drawn to a method for detecting in a sample the presence of a 254P1D6B-related protein or a 254P1D6B-related polynucleotide comprising contacting the sample with a substance that specifically binds to SEQ ID NO:5 or the polynucleotide encoding SEQ ID NO:5, classified in class 435, subclasses 6 and 7.1.

12. Claims 21-27 in part, drawn to a method for detecting in a sample the presence of a 254P1D6B-related protein or a 254P1D6B-related polynucleotide comprising contacting the sample with a substance that specifically binds to SEQ ID NO:7 or the polynucleotide encoding SEQ ID NO:7, classified in class 435, subclasses 6 and 7.1.

13. Claims 21-27 in part, drawn to a method for detecting in a sample the presence of a 254P1D6B-related protein or a 254P1D6B-related polynucleotide comprising contacting the sample with a substance that specifically binds to SEQ ID NO:11

or the polynucleotide encoding SEQ ID NO:11, classified in class 435, subclasses 6 and 7.1.

14. Claims 21-27 in part, drawn to a method for detecting in a sample the presence of a 254P1D6B-related protein or a 254P1D6B-related polynucleotide comprising contacting the sample with a substance that specifically binds to SEQ ID NO:1 or the polynucleotide encoding SEQ ID NO:1, classified in class 435, subclasses 6 and 7.1.

15. Claims 31-33 and 39, all in part, drawn to composition comprising an antibody or fragment thereof which modulates the status of the protein of SEQ ID NO:3, a hybridoma producing said antibody and a composition comprising a polynucleotide encoding said antibody or fragment thereof, classified in class 435, subclasses 326 and 346, class 530, subclass 387.1 and class 536, subclass 23.53.

16. Claims 31-33 and 39, all in part, drawn to composition comprising an antibody or fragment thereof which modulates the status of the protein of SEQ ID NO:5, a hybridoma producing said antibody and a composition comprising a polynucleotide encoding said antibody or fragment thereof, classified in class 435, subclasses 326 and 346, class 530, subclass 387.1 and class 536, subclass 23.53.

17. Claims 31-33, 39, all in part, drawn to composition comprising an antibody or fragment thereof which modulates the status of the protein of SEQ ID NO:7, a hybridoma producing said antibody and a composition comprising a polynucleotide encoding said antibody or fragment thereof, classified in class 435, subclasses 326 and 346, class 530, subclass 387.1 and class 536, subclass 23.53.

18. Claims 31-33, 39, all in part, drawn to composition comprising an antibody or fragment thereof which modulates the status of the protein of SEQ ID NO:11, a hybridoma producing said antibody and a composition comprising a polynucleotide encoding said antibody or fragment thereof, classified in class

435, subclasses 326 and 346, class 530, subclass 387.1 and class 536, subclass 23.53.

19. Claim 40 in part, drawn to a composition comprising a ribozyme which modulates the status of the protein of SEQ ID NO:3 and a composition comprising a nucleic acid which encodes said ribozyme, classified in class 435, subclass 183 and class 536, subclass 24.5.

20. Claim 40in part, drawn to a composition comprising a ribozyme which modulates the status of the protein of SEQ ID NO:5 and a composition comprising a nucleic acid which encodes said ribozyme, classified in class 435, subclass 183 and class 536, subclass 24.5.

21. Claim 40 in part, drawn to a composition comprising a ribozyme which modulates the status of the protein of SEQ ID NO:7 and a composition comprising a nucleic acid which encodes said ribozyme, classified in class 435, subclass 183 and class 536, subclass 24.5.

22. Claim 40 in part, drawn to a composition comprising a ribozyme which modulates the status of the protein of SEQ ID NO:11 and a composition comprising a nucleic acid which encodes said ribozyme, classified in class 435, subclass 183 and class 536, subclass 24.5.

23. Claim 41 in part, drawn to a composition comprising a T-cell which modulates the status of SEQ ID NO:3 or is modulated by SEQ ID NO:3, classified in class 435, subclasses, 325, 355 and 372.3.

24. Claim 41 in part, drawn to a composition comprising a T-cell which modulates the status of SEQ ID NO:5 or is modulated by SEQ ID NO:5, classified in class 435, subclasses, 325, 355 and 372.3.

25. Claim 41 in part, drawn to a composition comprising a T-cell which modulates the status of SEQ ID NO:7 or is modulated by SEQ ID NO:7, classified in class 435, subclasses, 325, 355 and 372.3.

26. Claim 41 in part, drawn to a composition comprising a T-cell which modulates the status of SEQ ID NO:11 or is modulated by SEQ ID NO:11, classified in class 435, subclasses, 325, 355 and 372.3.

27. Claims 38, 43 and 48, all in part, drawn to a method of delivering a cytotoxic agent comprising administering the cytotoxic agent conjugated to an antibody which binds to SEQ ID NO:3 and method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:3 comprising administering an antibody or fragment thereof which specifically binds to SEQ ID NO:3 or a vector which encodes a single chain monoclonal antibody which binds to SEQ ID NO:3, classified in class 424, subclass 130.1 and class 514, subclass 44.

28. Claims 38, 43 and 48, all in part, drawn to a method of delivering a cytotoxic agent comprising administering the cytotoxic agent conjugated to an antibody which binds to SEQ ID NO:5 and a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:5 comprising administering an antibody or fragment thereof which specifically binds to SEQ ID NO:5 or a vector which encodes a single chain monoclonal antibody which binds to SEQ ID NO:5, classified in class 424, subclass 130.1 and class 514, subclass 44.

29. Claims 38, 43 and 48, all in part, drawn to a method of delivering a cytotoxic agent comprising administering the cytotoxic agent conjugated to an antibody which binds to SEQ ID NO:7 and a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:7 comprising administering an antibody or fragment thereof which specifically binds to SEQ ID NO:7 or a vector which encodes a single chain monoclonal antibody which binds to SEQ ID NO:7, classified in class 424, subclass 130.1 and class 514, subclass 44.

30. Claims 38, 43 and 48, all in part, drawn to a method of delivering a cytotoxic agent comprising administering the cytotoxic agent conjugated to an antibody which binds to SEQ ID NO:11 and a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:11 comprising administering an antibody or fragment thereof which specifically binds to SEQ ID NO:11 or a vector which encodes a single chain monoclonal antibody which binds to SEQ ID NO:11, classified in class 424, subclass 130.1 and class 514, subclass 44.

31. Claim 46 in part, drawn to a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:3 comprising administering a ribozyme

that cleaves a polynucleotide encoding SEQ ID NO:3, classified in class 424, subclass 94.1 and class 514, subclass 44.

32. Claim 46 in part, drawn to a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:5 comprising administering a ribozyme that cleaves a polynucleotide encoding SEQ ID NO:5, classified in class 424, subclass 94.1 and class 514, subclass 44.

33. Claim 46 in part, drawn to a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:7 comprising administering a ribozyme that cleaves a polynucleotide encoding SEQ ID NO:7, classified in class 424, subclass 94.1 and class 514, subclass 44.

34. Claim 46 in part, drawn to a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:11 comprising administering a ribozyme that cleaves a polynucleotide encoding SEQ ID NO:11, classified in class 424, subclass 94.1 and class 514, subclass 44.

35. Claim 47 in part, drawn to a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:3 comprising administering human T cells to said cancer cells, wherein said T-cells specifically recognize a peptide subsequence of SEQ ID NO:3, classified in class 424, subclass 93.71.

36. Claim 47 in part, drawn to a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:5 comprising administering human T cells to said cancer cells, wherein said T-cells specifically recognize a peptide subsequence of SEQ ID NO:5, classified in class 424, subclass 93.71.

37. Claim 47 in part, drawn to a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:7 comprising administering human T cells to said cancer cells, wherein said T-cells specifically recognize a peptide subsequence of SEQ ID NO:7, classified in class 424, subclass 93.71.

38. Claim 47 in part, drawn to a method of inhibiting growth, reproduction or survival of cancer cells that express SEQ ID NO:11 comprising administering human T cells to said cancer cells, wherein said T-cells specifically recognize a peptide subsequence of SEQ ID NO:11, classified in class 424, subclass 93.71.

39. Claim 34, in part, drawn to a non-human transgenic animal that produces an antibody or fragment thereof that binds to SEQ ID NO:3, classified in class 800, subclass 8.

40. Claim 34, in part, drawn to a non-human transgenic animal that produces an antibody or fragment thereof that binds to SEQ ID NO:5, classified in class 800, subclass 8.

41. Claim 34, in part, drawn to a non-human transgenic animal that produces an antibody or fragment thereof that binds to SEQ ID NO:7, classified in class 800, subclass 8.

42. Claim 34, in part, drawn to a non-human transgenic animal that produces an antibody or fragment thereof that binds to SEQ ID NO:11, classified in class 800, subclass 8.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-5 are structurally and functionally different protein sequences and polynucleotides encoding said sequences. Because each polypeptide has a specific amino acid sequence which is unrelated to another of SEQ ID NO:1, 3, 5, 7 or 11, each protein is structurally distinct. The search for a single SEQ ID NO:1, 3, 5, 7 or 11 and peptides derived from said proteins in both the literature and the electronic sequence databases would not be co-extensive with the search for any other SEQ ID NO:1, 3, 5, 7 or 11 and peptides thereof, therefore there would be undue burden on the examiner and the resources of the PTO to search all of the protein sequences in a single application. Likewise the antibodies of Groups 15-18 differ from one another in that each antibody binds to a specific protein, the ribozymes of Groups 19-22 all differ from each other in that said ribozymes cleave a polynucleotide encoding a specific protein, the T-cells of Groups 23-26 all differ with respect to the recognitions of a peptide which is a fragment of a specific protein and the transgenic animals of Groups 39-42. Thus, the search for an antibody which binds to SEQ ID NO:3 would not be-coextensive for the antibodies which bind to SEQ ID NO:5, 7 and 11; a search for a ribozyme which cleaved the polynucleotides encoding SEQ ID NO:3 would not be co-extensive with the ribozymes which cleaved SEQ ID NO:5, 7 and 11,a search for T-cells which recognized peptides of SEQ ID NO:3 would not be

coextensive with a search for T-cells which recognized SEQ ID NO:5, 7 or 11 and a search for a transgenic animal which produces an antibody which binds to SEQ ID NO:3 would not be co-extensive with a search for a transgenic animal that produces an antibody which binds to SEQ ID NO:5, 7 or 11.. With the same reasoning, the methods of Groups 10-14 differ from each other by dependence on a specific polypeptide of SEQ ID NO:1, 3, 5, 7 and 11 or the nucleic acid encoding said specific polypeptide, and the methods of Groups 6-9, 27-30, 31-34 and 38 are each distinct from each other being dependent upon a specific polypeptide, or a polynucleotide encoding a specific peptide.

Inventions of peptides (Groups 1-5), antibodies (Groups 15-18), ribozymes (Groups 19-22), T-cells (Groups 23-26) and non-human transgenic animals (Groups 39-42) are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups 6-9, 10-14 and 27-38 differ in the method objectives, method steps and parameters and in the reagents used. The method objective for Groups 10-14 is the detection of a 254P1D6B related protein or polynucleotide in a sample. The method objective for Groups 6-9 and 27-38 is the method of generating an immune response in a mammal and/or the inhibition of the growth reproduction or survival of cancer cells. Thus Groups 10-14 differ completely in both method objective and method steps. Groups 6-9, 27-30, 31-34 and 35-38 differ from each other in the reagents used in the active method steps: Groups 6-9 require the administration of a peptide or protein; Groups 27-30 require the administration of an antibody; Groups 31-34 require the administration of a ribozyme; and Groups 35-38 require the administration of a T-cell. Thus each method is distinct because of the requirement of different method steps using different reagents.

Inventions of Groups 1-4 and 6-9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides and proteins of Groups 1-4 can be

used in a process to make antibodies, or used to pulse dendritic cells; and the polynucleotides of Groups 1-4 can also be used in the method of Groups 10-13.

Inventions of Groups 15-18 and 27-30 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Groups 15-18 can be used in the method of Groups 10-13, and can also be used in a method to make an anti-idiotypic antibody.

Inventions of Groups 19-22 and 31-34 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ribozymes of Groups 19-22 can be used in an in vitro diagnostic assay.

Inventions of Groups 23-26 and 35-38 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the T-cells of Groups can be used in an in vitro assay to determine conditions of evoking immunotolerance versus immunostimulation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

5. Claims 28-30, 36 and 37, as drawn to a composition which modulates the status of a cell that expresses SEQ ID NO:3, link(s) inventions 15, 19 and 23; claims 28-30, 36 and 37,as drawn to a composition which modulates the status of a cell that expresses SEQ ID NO:5 link(s) inventions 16, 20 and 24; claims 28-30, 36 and 37,as drawn to a composition which modulates

the status of a cell that expresses SEQ ID NO:7 link(s) inventions 17, 21 and 25; claims 28-30, 36 and 37,as drawn to a composition which modulates the status of a cell that expresses SEQ ID NO:11 link(s) inventions 18, 22 and 26. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 28-30, 36 and 37 to the extent that the claims read on a composition which modulates the status of a cell that expresses a specific SEQ ID NO:3, 5, 7 or 11. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) to the extent that the claims read on a single SEQ ID NO: 3, 5, 7 or 11will be entitled to exami-nation in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Claim 42, as drawn to a method of inhibiting the growth, reproduction or survival of cancer cells which express SEQ ID NO:3, link(s) inventions 6, 27, 31 and 38; claim 42,as drawn to a method of inhibiting the growth, reproduction or survival of cancer cells which express SEQ ID NO:5 link(s) inventions 7, 28, 32 and 36; claim 42,as drawn to a method of inhibiting the growth, reproduction or survival of cancer cells which express SEQ ID NO:7 link(s) inventions 8, 29, 33 and 37; claim 42,as drawn to a method of inhibiting the growth, reproduction or survival of cancer cells which express SEQ ID NO:11 link(s) inventions 9, 30, 34 and 38. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim42 to the extent that the claims read on a method of inhibiting the growth, reproduction or survival of cancer cells which express a specific SEQ ID NO:3, 5, 7 or 11 and on a method of generating an immune response to a specific SEQ ID NO:3, 5, 7 or 11. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) to the extent that the claims read on a method reliant on a single SEQ

ID NO: 3, 5, 7 or 11will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D
6/23/2005

KAREN A. CANELLA PH.D
PRIMARY EXAMINER